

## Section II (Remarks)

### A. Summary of Amendment to the Claims

By the present Amendment, claims 28, 32, 35, 44, and 50 have been amended, and new claims 53-58 have been added. Claims 1-23 and 33 were previously cancelled. No new matter within the meaning of 35 U.S.C. §132(a) has been introduced by the foregoing amendments.

The amendments made herein are fully consistent with and supported by the originally-filed disclosure of this application.

With respect to the feature of an empty detect gas being “compositionally different” from a headspace gas, such features is supported by the specification, for example, at page 7, lines 20 – 26, which refer to a headspace gas including oxygen useful to scavenge free radicals in color filter chemical, removal of the oxygen-containing headspace gas as being no longer needed or desired for supply of the color filter chemical to a manufacturing process; and page 12, lines 4-19, which refer to removal of headspace gas as detrimental to a manufacturing process, and addition of a small amount of [different] empty detect gas after removal of the headspace gas, with the empty detect gas being detectable by an empty detect gas sensor 62.

With respect to the feature of an empty detect sensor being adapted to preferentially detect empty detect gas, such feature is supported by the specification, for example, at page 3, lines 24-30, which refer to an “**empty detect gas sensor** [that] **senses *this* empty detect gas** when the liquid chemical has been exhausted from the container.”

With respect to the feature of a gas passage being selectively coupleable to a headspace gas drain and a source of empty detect gas, such feature is supported by the specification, for example, at Figure 2 and text relating thereto.

With respect to a “forcing element,” such feature is supported by the specification, for example, at paragraph [0019], which refers to “means capable of collapsing inner container 20 to force headspace gas 18 through gas passage 34.”

With respect to the feature of a source of empty detect gas that is distinct from a forcing element, such feature is supported by the specification, for example, at Figure 2 and text relating thereto.

#### **B. Subject Matter Acknowledged to be Allowable**

In the March 19, 2008 Office Action, claims 24-31 were allowed, and claims 41-42 and 47-49 were objected to as being dependent upon a rejected base claim, but were indicated to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### **C. Response to Claim Rejections Under 35 U.S.C. 102(b)**

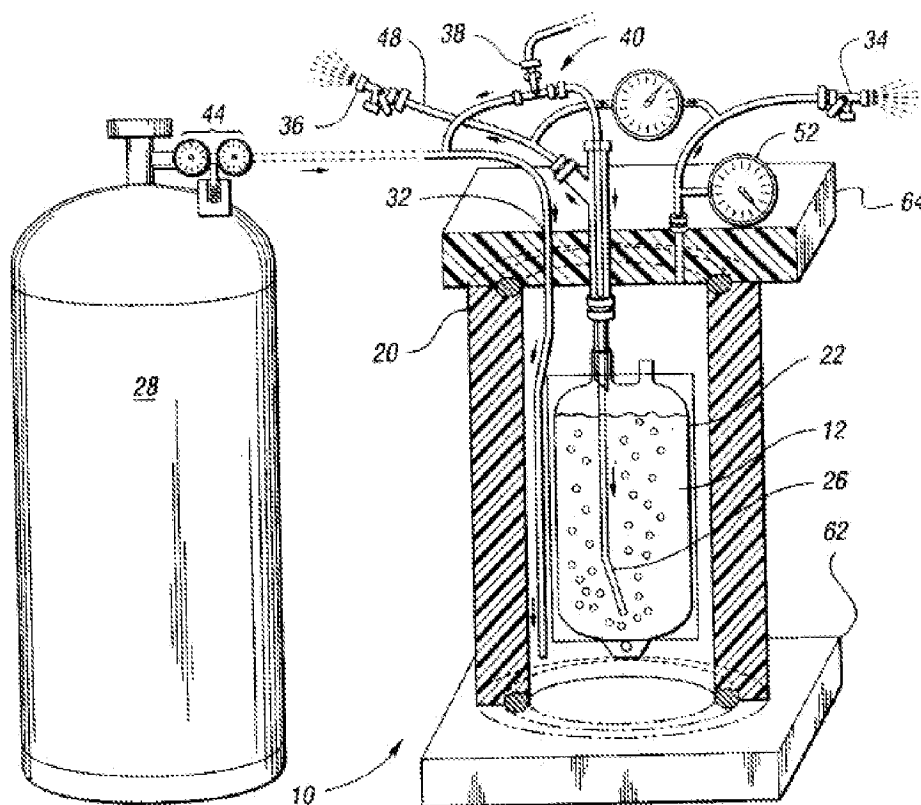
In the March 19, 2008 Office Action, claims 32, 34-39, 43-45, 50, and 52 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,693,017 to Spears et al. (“Spears”). Such rejections are traversed in application to the claims as amended herewith.

##### **1. Law Regarding Anticipation Rejections under 35 U.S.C. § 102**

“Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration.” *W.L. Gore & Assocs. v. Garlock*, 721 F.2d 1540, 220 USPQ 303, 313 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). It is not enough that the prior art reference disclose all the claimed elements in isolation. Rather, “**anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim.**” *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984) (emphasis added). Further, “[u]nder 35 U.S.C. § 102, anticipation requires that ... the prior art reference must be enabling, thus placing the allegedly disclosed matter in the possession of the public.” *Akzo, N.V. v. United States Int’l Trade Comm’n*, 808 F.2d 1471, 1 USPQ2d 1241, 1245 (Fed. Cir. 1986).

##### **2. Disclosure of Spears**

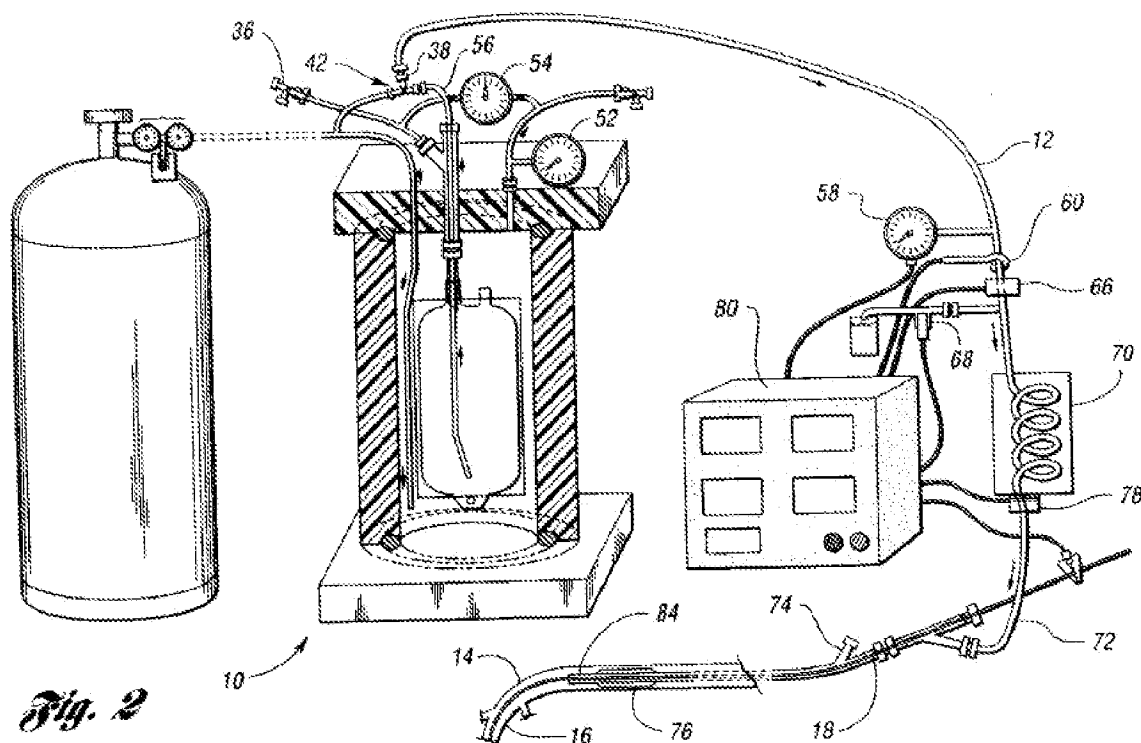
Spears system and method for generating an oxygen-supersaturated physiologic solution (e.g., blood) without bubbles therein for delivery to a patient’s blood vessel. Figure 1 of Spears is reproduced below.



Referring to Spears FIG. 1, a gas-tight vessel 20 has disposed therein a collapsible container 22 (e.g. a blood bag), and a space 24 is provided between the container 22 and the vessel 20 to enable the collapsible container 22 to expand. A trocar 26 is inserted into the collapsible container and supplies oxygen to the fluid contents of such container 22 to drive oxygen into the solution. The same oxygen source (canister shown at left in Spears FIG. 1) is also used as a hydrostatic pressure source to pressurize the space between the vessel 20 and the collapsible container 22 to (a) dissolve all bubbles within the physiologic solution; and (b) deliver the oxygen-supersaturated solution at a desired flow rate through the delivery tube 56. (Spears, col. 3, line 66 – col. 4, line 4; col. 5, lines 32-35.) Thus, Spears provides that “a small tank of oxygen can be used to oxygenate a physiologic solution and provide the hydrostatic pressure for delivering the solution through the catheter.” (Spears, col. 5, lines 48-51.)

A container exit valve 36 controls the rate of escape of oxygen venting from the container 22, and an adjustable space exit valve 34 (apparently at upper right of container 20, but not labeled in Spears FIG. 1) enables monitoring of pressure within the space 24 inside the container 20.

Referring to Spears FIG. 2 (reproduced below), Spears discloses that a “**bubble detector 66**” may be provided in communication with the delivery tube 56. (Spears, col. 4, lines 5-8).



As a secondary bubble detection mechanism, Spears further discloses the monitoring of an ECG by a guide wire within an angioplasty catheter, as such bubbles markedly reduce EDG signal within 0 to 2 seconds, and such signal reduction may be linked to an automatic delivery shutoff mechanism to prevent embolism and patient injury. (Spears, col. 5, line 63 – col. 6, line 10).

### 3. Patentable Distinctions of Claims 32, 34-39, 43-45, 50, and 52 Over Spears

Claims 32, 34-39, 43-45, 50, and 52 comprise four independent claims, namely, independent apparatus / system claims 32, 44, and 50, and independent method claim 35. Each of these four independent claims has been amended herewith.

Independent apparatus (connector) **claim 32** recites, *inter alia*:

“... an empty detect gas sensor adapted to sense an empty detect gas introduced into the interior of the inner container immediately prior to dispensing of the liquid to the manufacturing process, wherein the empty detect gas is compositionally different from the headspace gas, and the empty detect gas

sensor is adapted to preferentially detect said empty detect gas as compared to said headspace gas.”

At least the foregoing underlined portion of the claim 32 distinguishes Spears. Spears discloses supply of a single gas (oxygen) and removal of the same gas (oxygen) from a blood oxygenation apparatus. **Nothing in Spears teaches or remotely suggests use of an empty detect gas that is compositionally different from a headspace gas.** To the contrary, Spears teaches the singular use of oxygen to contact physiologic solutions.

With respect to gas detection, Spears discloses two forms of **bubble detection** – namely, bubble sensor 66, and electrical bubble detection with an ECG apparatus. **Nothing in Spears suggests any detection technology capable of preferential detection based on composition of gas to be detected.**

Independent system **claim 44** recites, *inter alia*:

... a connector attachable to the container, the connector including a probe insertable into the inner container and defining a flow passage therein, the connector further including a gas passage in fluid communication with the interior of the inner container, wherein the gas passage is selectively coupleable to a headspace gas drain and a source of empty detect gas;

...and an empty detecting gas sensor adapted to sense an empty detect gas introduced from the source of empty detect gas to the interior of the inner container immediately prior to dispensing of the liquid to the manufacturing process;

wherein the forcing element is distinct from the source of empty detect gas.

At least the foregoing underlined portion of the claim 44 distinguishes Spears. Nothing in Spears discloses any source of empty detect gas that is distinct from a separate forcing element, let alone a gas passage that is “selectively coupleable to a headspace gas drain and a source of empty detect gas.” Spears discloses that a single oxygen source is used to supply oxygen to the interior container 22 to oxygenate a physiologic solution therein, and to pressurize the space between the vessel 20 and the collapsible container 22 compress the collapsible container 22. (E.g., Spears, col. 3, line 66 – col. 4, line 4; col. 5, lines 32-35.) As Spears uses a unitary oxygen source for both oxygenation and pressure dispensation, Spears teaches away from use of a forcing element that is distinct from an empty detect gas source.

Independent system **claim 50** recites, *inter alia*:

... a connector attachable to the container, the connector including a probe insertable into the inner container and defining a flow passage therein, the connector further including a gas passage in fluid communication with the interior of the inner container, wherein the gas passage is selectively coupleable to a headspace gas drain and a source of empty detect gas;

a fluid source in fluid communication with a space between inner walls of the outer container and the inner container for causing fluid under pressure to flow into the space between the inner walls of the outer container and the inner container to force the headspace gas out of the inner container via the gas passage to a headspace gas drain and to force liquid out of the inner container through the flow passage to the manufacturing process; and

... wherein the source of empty detect gas is distinct from the fluid source.

Independent claim 50 is distinguished over Spears for substantially the same reasons as articulated in connection with claim 44. Nothing in Spears discloses any source of empty detect gas that is distinct from a separate (e.g., dispensation) fluid source, let alone a gas passage that is “selectively coupleable to a headspace gas drain and a source of empty detect gas.” Spears discloses that a single oxygen source is used to supply oxygen to the interior container 22 to oxygenate a physiologic solution therein, and to pressurize the space between the vessel 20 and the collapsible container 22 compress the collapsible container 22. As Spears uses a unitary oxygen source for both oxygenation and pressure dispensation, Spears teaches away from use of a fluid source that is distinct from an empty detect gas source.

Independent method **claim 35** recites steps of a method including:

...evacuating the headspace gas from the inner container;  
following said evacuating step, introducing an amount of empty detect gas into  
the inner container; and  
compressing the inner container to force liquid from the inner container.

Spears fails to teach the introduction of *any* gas – let alone an empty detect gas – into an inner container after headspace gas is evacuated and prior to pressure dispensation of liquid therefrom. To the contrary, Spears discloses that gas flow is stopped, and then all gas pockets are driven out of the top of the inner container immediately prior to liquid dispensation. See Spears, col. 5, lines 17-24, as reproduced below:

Once the solution in the bag 22 has reached the target partial pressure of oxygen, **flow through the dip trocar 26 is stopped** and the **oxygen pressure external to the bag is increased slightly to drive out any pockets at the top of the bag.** The **same source of oxygen is then used to increase the oxygen pressure in the vessel 20 to provide hydrostatic pressure for achieving liquid flow rates required for the coronary artery application.**

In this regard, Spears **teaches away** from any introduction of empty detect gas into the inner container following said evacuating step, as required by amended claim 35.

Based on the foregoing, Spears fails to disclose “each and every element of the claimed invention, arranged as in [Applicant’s independent claims 32, 40, 44, and 35]” as required to support any rejection under 35 U.S.C. 102. As dependent claims inherently include all limitations of the claims on which they depend, the claims depending from 32, 40, 44, and 35 are likewise distinguished over Spears. Accordingly, withdrawal of the rejections under 35 U.S.C. 102 is warranted, and is respectfully requested.

#### **D. Response to Claim Rejections Under 35 U.S.C. 103(a)**

In the March 19, 2008 Office Action, claims 40, 46, and 51 were rejected under 35 U.S.C. 103(a) as being unpatentable for obviousness over Spears in view of U.S. Patent No. 4,313,419 to Lyon et al. (“Lyon”). Such rejections are traversed in application to the claims as amended herewith.

##### **I. Law Regarding Obviousness Rejections Under 35 U.S.C. § 103**

To support a rejection under 35 U.S.C. 103, **the prior art reference(s) must teach all of the limitations of the claims.** MPEP § 2143.03.

In considering a reference for its effect on patentability, the reference is required to be considered in its entirety, including portions that **teach away** from the invention under consideration. Simply stated, the prior art must be considered as a whole. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984) (emphasis added); MPEP § 2141.02. “It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.” *Application of Wesslau*, 353

F.2d 238, 241 (C.C.P.A. 1965); *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve*, 796 F.2d 443, 448 (Fed. Cir. 1986), cert. denied, 484 U.S. 823 (1987). The Federal Circuit and its predecessor court have repeatedly held that if references taken in combination would produce a ‘seemingly inoperative’ device, then such references teach away from the combination and cannot serve as predicates for a *prima facie* case of obviousness. *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 60 USPQ2d 1001, 1010 (Fed. Cir. 2001); *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984); *In re Spinnoble*, 405 F.2d 578, 587, 160 USPQ 237, 244 (C.C.P.A. 1969).

According to the recent U.S. Supreme Court decision in *KSR International Co. v. Teleflex Inc.*, 127 S.Ct 1727, 167 L.Ed.2d 705, 82 USPQ2d 1385 (April 30, 2007), the court did not disavow the previous “teaching, motivation or suggestion” or “TSM” test, but stated that such TSM text *should not be strictly applied* in determining obviousness. In connection with this point, the Supreme Court stated that:

**“A patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art. ... [Rather], it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant art to combine the [prior art] elements in the manner claimed.”** *KSR*, 82 USPQ2d at 1389.

It is fundamental to a proper rejection of claims under 35 U.S.C. § 103 that an examiner must present a convincing line of reasoning supporting the rejection. MPEP 2144 (“Sources of Rationale Supporting a Rejection Under 35 U.S.C. 103”), citing *Ex parte Clapp*, 227 USPQ 972 (Bd. Pat. App. & Inter. 1985). The Supreme Court in *KSR* affirmed the validity of such approach, stating that **“there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”** *KSR*, 82 USPQ2d at 1396.

In *KSR*, the Supreme Court further confirmed that references that teach away from the invention are evidence of the non-obviousness of a claimed invention, (*KSR*, 82 USPQ2d at 1395, 1399) and reaffirmed the principle that a factfinder judging patentability “should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning.”



2. Patentable Distinctions of Claims 40, 46, and 51 Over the Cited Art

Claims 40, 46, and 51 depend from independent claims 35, 44, and 50, respectively. The patentable distinctions of independent claims 35, 44, and 50 over Spears has been demonstrated hereinabove. Nothing in Lyon remedies the deficiencies of Spears in disclosing the elements of Applicant's independent claims as amended herewith. As claims 40, 46, and 51 inherently include all the limitations of independent claims 35, 44, and 50, respectively, claims 40, 46, and 51 are likewise distinguished over Spears and Lyon. Accordingly, withdrawal of the rejections under 35 U.S.C. 103 is warranted, and is respectfully requested.

**E. Distinctions of New Independent Claim 54 Over the Cited Art**

New claims 54 and 55 are similar in character to claims 47 and 49, which were previously indicated to be allowable if rewritten in independent form. New claim 54 includes all of the limitations of prior claim 47 except for the empty detect gas sensor; however, since the examiner suggested that an empty detect gas sensor was disclosed by Spears, such empty detect gas sensor was apparently not a basis for the examiner's prior indication that prior claim 47 was allowable over the art of record. As the examiner has already indicated that prior claim 47 was allowable, new independent claim 54, together with new claim 55 depending therefrom, are believed to be similarly allowable over the art. Allowance of such claims is respectfully requested.

**F. Fee Payable for Added Claims**

By the present Amendment, 1 new independent claims and 6 new total claims have been introduced, beyond the numbers for which payment was previously made. Fees applicable to a large entity payable for such added claims are calculated as follows:  $(1 \times \$210.00) + (6 \times \$50.00) = \underline{\$510.00}$ . Online payment of such fees is being made herewith via credit card.

**CONCLUSION**

Based on the foregoing, all of Applicants' pending claims are patentably distinguished over the art, and in form and condition for allowance. The examiner is requested to favorably consider the foregoing, and to responsively issue a Notice of Allowance. If any issues require further resolution, the examiner is requested to contact the undersigned attorney at (919) 419-9350 to discuss same.

Respectfully submitted,

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